REMARKS

I. Status of the Application

This paper responds to a non-final Office action, which was mailed on January 27, 2005. The original application was filed with claims 1-17. In a response to a telephonic restriction requirement, Applicant elected to pursue Group I invention (claims 1-9) and gabapentin species. A non-final Office action mailed on September 13, 2001 rejected claims 1-9 and withdrew from consideration claims 10-17 as being drawn to a non-elected invention. Applicant filed a response to the non-final Office action on February 12, 2002, amending claims 1-9 and adding new claims 18-22. A subsequent final Office action mailed on May 30, 2002, rejected claims 1-9 and 18-22. Applicant filed an after-final amendment on July 30, 2002, which was not entered. Applicant subsequently filed a Request for Continued Examination (RCE), which amended claim 1 and added new clams 23 and 24. A non-final Office action was mailed on April 10, 2003, which rejected claims 1-9 and 18-22. Applicant filed a response on September 10, 2003, which amended claims 1, 9, 18, 20, and 24, and canceled claims 10-17. Following a final Office action, application filed an RCE, which canceled claims 1-9 and 18-24 and added new claims 25-31.

This paper amends claim 25 and adds new claim 33. Applicant respectfully requests reconsideration of claims 25-33 in view of the above amendment and the following remarks. By the action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Petition for One-Month Extension of Time Under 37 CFR § 1.136(a)

The paper responds to an Office action mailed on January 27, 2005 that set a three-month shortened statutory period for reply. Applicant is filing this response on May 27, 2005, within one following the expiration of the three-month period for reply. Accordingly, Applicant hereby petitions for a one-month extension of time in which to reply and has enclosed the requisite fee under 37 CFR § 1.17(a)(1) in a Fee Transmittal that accompanies this response.

III. Amendment of Claims 25, 29 and 30, and Addition of New Claim 33

Claim 25 has been amended to clarify that the "pharmaceutical" composition includes an α-amino acid "for stabilizing the composition" and an auxiliary agent "which is not water." Claims 25, 29, and 30 have been amended to eliminate references to a "pharmaceutical dosage form." New claim 33, which includes the limitations of claim 25, recites that the composition includes water.. These amendments are fully supported in the application as filed. See, e.g., the Application at page 6, lines 1-12, and page 36, lines 1-4. Therefore, Applicant submits that none of these changes introduce new matter.

IV. Rejection of Claims 25-27, 29 and 31 Under 35 U.S.C. § 102

The Office action rejected claims 25-27, 29 and 31 under 35 U.S.C. § 102(b) as allegedly being anticipated by Woodruff (US 5,084,479) because it "discloses a solution comprising N-methyl-D-aspartic acid and gabapentin (column 8, line 5)." As noted above in section III of this paper, Applicant has added claim 25, which requires that the claimed composition include an auxiliary agent which is not water. None of the solutions containing N-methyl-D-aspartic acid include an auxiliary agent which is not water, and therefore Woodruff cannot anticipate the claims.

Furthermore, Woodruff cannot be used to render claims 25-33 obvious because it teaches away from any pharmaceutical dosage form that includes N-methyl-D-aspartic acid (NMDA), gabapentin, and an auxiliary agent. In Woodruff, solutions of gabapentin and NMDA were apparently used to show that gabapentin reduces depolarization of paraventricular thalamus neurons due to NMDA (column 8, lines 20-49). As described in Woodruff, "these results indicate that gabapentin has additional therapeutic indications . . . [since] over stimulation of NMDA receptors has been implicated in the etiology of neuronal damage induced by anoxia, stroke, hypoglycemia, Huntington's disease, as well as epilepsy" (column 3, lines 9-14). Since Woodruff teaches that gabapentin counteracts the effects of NMDA, and over stimulation of NMDA receptors has been implicated in neuronal damage, adding NMDA to a pharmaceutical preparation containing gabapentin would run counter to Woodruff's teachings. Applicant therefore submits that all of the claims of the present application are patentable over Woodruff.

V. Rejection of Claims 25-31 Under 35 U.S.C. § 103

The final Office action rejected claims 25-31 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Seiler et al. (Gen. Pharmac. Vol. 15, No. 4, pp 367-69, 1984) in view of Costa et al. (US 5,248,678) and if necessary, Liu et al., European Journal of Pharmacology 182:109-115 (1990).

Applicant respectfully submits that the rejection, as now applied to claims 25-33, is improper because it does not establish a prima facie case of obviousness. To establish a prima facie case of obviousness, there must be (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; there must be (2) a reasonable expectation of success; and (3) the reference (or references when combined) must teach or suggest all the claim limitations. See, MPEP § 2143.01 (Feb. 2003). Applicant respectfully submits that there is no suggestion or motivation to combine Seiler et al. and Costa et al. or Liu et al.

As an initial matter, Applicant reiterates that Costa et al. and Liu et al. cannot be combined with Seiler et al. because the latter reference teaches away from the combination. According to the Office action, "Seiler et al. teaches or suggests the synergistic anticonvulsant effects of a GABA agonist and alpha-amino acid such as glycine. The reference discloses muscimol as the specific example of a GABA agonist." Seiler et al, however, warns against administering muscimol and glycine together so as "to avoid the potential inhibition of muscimol absorption by glycine" (page 367, Methods section). Thus, not only does Seiler et al. fail to teach or suggest combining gabapentin and an α-amino acid, it teaches away from making a pharmaceutical preparation comprised of gabapentin and an α amino acid. Furthermore, although the Office action contends that Liu et al. "demonstrates the use of alpha-amino acid such as glycine in potentiating GABA agonist such as vigabatrin," nothing in Liu et al. teaches or suggests that glycine would not also inhibit vigabatrin absorption if administered at the same time.

The final Office action's contention that "one having ordinary skill in the art would have been motivated to make such modification [to Seilor et al.] such that the combination of

gabapentin and glycine in a composition would provide synergistic anticonvsulant effect" represents an impermissible "obvious to try" rationale. GABA agonists potentially embrace a large number of compounds. Indeed, Costa et al. lists a number of compounds purported to be GABA agonists, but besides muscimol, none of the cited references indicate that glycine may improve the compounds' anticonvulsive properties. Moreover, Peterson et al., Neuropharmacology 29(4):399-409 (1990), which was cited in a prior Office action indicates that the potency and selectivity of a number of anticonvulsants—including sodium divalproate (valproic acid) which is listed in Costa et al.—are unaffected by glycine. Thus, far from teaching a "pharmaceutical preparation comprising GABA agonist and glycine," the cited references teach that glycine improves the anticonvulsive properties of a few GABA agonists, namely, muscimol and γ vinyl GABA, which is insufficient to support an obviousness rejection.

Furthermore, nothing in the references teaches or suggests that an α-amino acid would stabilize a pharmaceutical composition containing either gabapentin or pregabalin. As shown in the Examples, the inclusion of an α-amino acid in compositions containing gabapentin (Examples 1-7) or pregabalin (Examples 8-10) dramatically decreases lactam formation. This result is surprising and completely unexpected, and therefore Applicant submits that the claimed invention is patentable over the cited references.

VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant submits that all fees associated with the filing of this paper have been identified in a fee transmittal that accompanies this amendment. However, if any fees required in connection with the filing of this paper have not been identified in the accompanying transmittal, please charge such fees to deposit account number 23-0455.

Respectfully submitted,

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